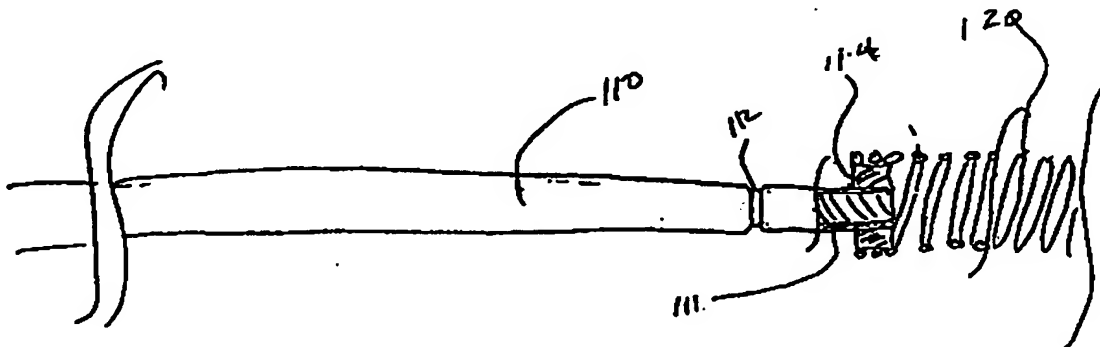




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/12, A61F 2/01, 2/06		A1	(11) International Publication Number: WO 99/09894
			(43) International Publication Date: 4 March 1999 (04.03.99)
(21) International Application Number: PCT/US98/17885		T. [US/US]; 401 Encinal Avenue, Menlo Park, CA 94025 (US).	
(22) International Filing Date: 28 August 1998 (28.08.98)		(74) Agents: WHEELLOCK, E., Thomas et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).	
(30) Priority Data: 08/921,407 29 August 1997 (29.08.97) US 08/941,458 30 September 1997 (30.09.97) US		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 08/941,458 (CIP) Filed on 30 September 1997 (30.09.97)		Published With international search report.	
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(54) Title: FAST DETACHING ELECTRICALLY ISOLATED IMPLANT



## (57) Abstract

This is an implant for placement in the human body and an assembly for so placing that implant. Most desirably, it is an implant for use in the vasculature of the human body and is used to occlude some space in that vasculature as a portion of a treatment regimen. The implant itself is preferably a component of a deployment device using an electrolytically severable joint. The implant is electrically isolated from the electrolytically severable joint by a highly resistive or insulative layer. Such isolation and minimization of the conductive pathway from the placement apparatus to the body's fluids appears to enhance the susceptibility of the electrolytic joint to quick erosion and detachment of the implant from the deployment media. Although the implant itself is preferably a vaso-occlusive device, it may instead be a stent, a vena cava filter, or other implant which may be installed in this manner.

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## **FAST DETACHING ELECTRICALLY ISOLATED IMPLANT**

### **RELATED APPLICATIONS**

5           This is a continuation in part of U.S. Ser. No. 08/941,458, filed September 30, 1997, now pending which is a continuation-in-part of U.S. Ser. No. 08/921,407, filed August 29, 1997, now abandoned, the entirety of which are incorporated by reference.

### **FIELD OF INVENTION**

10           This invention is an implant for placement in the human body and an assembly for so placing that implant. Most desirably, it is an implant for use in the vasculature of the human body and is used to occlude some space in that vasculature as a portion of a treatment regimen. The implant itself is preferably a component of a deployment device or assembly using an electrolytically severable joint. The implant is electrically isolated  
15           from the electrolytically severable joint by a highly resistive or insulative layer. Such isolation and minimization of the conductive pathway from the placement apparatus to the body's fluids appears to enhance the susceptibility of the electrolytic joint to quick erosion and detachment of the implant from the deployment media. Although the implant itself is preferably a vaso-occlusive device, it may instead be a stent, a *vena cava* filter, or other  
20           implant which may be installed in this manner.

### **BACKGROUND OF THE INVENTION**

          Implants may be placed in the human body for a wide variety of reasons. For instance, stents are placed in a number of different lumens in the body. They may be  
25           placed in arteries to cover vascular lesions or to provide patency to the vessel. Stents are also placed in biliary ducts to prevent them from kinking or collapsing. Grafts may be used with stents to promote growth of endothelial tissue within those vessels.

*Vena cava* filters are implanted in the body, typically in the *vena cava*, to catch thrombus which are sloughed off from other sites within the body and which may be in the  
30           blood passing through the chosen site.

Vaso-occlusive devices or implants are used for a wide variety of reasons. They are often used for treatment of intra-vascular aneurysms. This is to say that the treatment involves the placement of a vaso-occlusive device in an aneurysm to cause the formation of a clot and eventually of a collagenous mass containing the vaso-occlusive device. These occlusions seal and fill the aneurysm thereby preventing the weakened wall of the aneurysm from being exposed to the pulsing blood pressure of the open vascular lumen.

Treatment of aneurysms in this fashion is a significant improvement over the surgical method typically involved. The surgical or extravascular approach is a common treatment of intra-cranial berry aneurysm; it is straightforward but fairly traumatic. The method involves removing of portion of the cranium and locating the aneurysm. The neck of the aneurysm is closed typically by applying a specially sized clip to the neck of the aneurysm. The surgeon may choose to perform a suture ligation of the neck or wrap the entire aneurysm. Each of these procedures is performed by an very intrusive invasion into the body and is performed from the outside of the aneurysm or target site. General anesthesia, craniotomy, brain retraction, and a placement of clip around the neck of the aneurysm all are traumatic. The surgical procedure is often delayed while waiting for the patient to stabilize medically. For this reason, many patients die from the underlying disease prior to the initiation of the surgical procedure.

Another procedure -- the extra - intravascular approach -- involves surgically exposing or stereotaxically reaching an aneurysm with a probe. The wall of the aneurysm is perforated from the outside and various techniques are used to occlude the interior of the aneurysm to prevent its rebleeding. The techniques used to occlude the aneurysm include electro-thrombosis, adhesive embolization, hoghair embolization, and ferromagnetic thrombosis. These procedures are discussed in U.S. Patent No. 5,122,136 to Guglielmi et al., the entirety of which is incorporated by reference.

Guglielmi et al. further describes an endovascular procedure which is at once the most elegant and least invasive. The procedure described in that patent includes a step in which the interior of the aneurysm is entered by the use of guidewire such as those in Engelson, U.S. Patent No. 4,884,579 and a catheter as in Engelson, U.S. Patent No. 4,739,768. These patents described devices utilizing guidewires and catheters which allow access to aneurysms from remote parts of the body. Typically, these catheters enter the

vasculature through the femoral artery in the groin. The Guglielmi et al system uses catheters and corewires which have a very flexible distal regions and supporting midsections which allow the combinations to be steerable to the region of the aneurysm. That is to say that the guidewire is first steered for a portion of the route to the aneurysm and the catheter is slid up over that guidewire until it reaches a point near the distal end of the guidewire. By steps, the catheter and guidewire are then placed at the mouth of the aneurysm. The catheter is introduced into the aneurysm and vaso-occlusive or embolism-forming devices may be delivered through the lumen.

Various vaso-occlusive devices are introduced through the noted microcatheters to close the aneurysm site. In some instances, a small balloon may be introduced into the aneurysm where it is inflated, detached, and left to occlude the aneurysm. Balloons are becoming less in favor because of the difficulty in introducing the balloon into the aneurysm sac, the possibility of aneurysm rupture due to over-inflation of the balloon within the aneurysm, and the inherent risk associated with the traction produced when detaching the balloon.

Another desirable embolism-forming device which may be introduced into aneurysm using end of vascular placement procedure is found in U.S. Patent No. 4,994,069 to Ritchart et al. In that patent are described various devices — typically platinum/tungsten alloy coils having very small diameters — which may be introduced into the aneurysm through a catheter such as those described in the Engelson patents above. These coils are often made of wire having a diameter of 2-6 mils. The coil diameter is often 10-30 mils. These soft, flexible coils, may be of any length desirable and appropriate for the site to be occluded. After these vaso-occlusive coils are placed in, e.g., a berry aneurysm, they first cause a formation of an embolic mass. This initial mass is shortly thereafter complemented with a collagenous material which significantly lessens the potential for aneurysm rupture.

There are variety of other vaso-occlusive devices, typically coils which may be delivered to the vascular site in a variety of ways, e.g., by mechanically detaching them from the delivery device. A significant number of these devices are described in patents owned by Target Therapeutics, Inc. For instance:

U.S. Patent No. 5,234,437, to Sepetka shows a method of unscrewing a helically wound coil from a pusher having interlocking surfaces.

U.S. Patent No. 5,250,071, to Palermo shows an embolic coil assembly using interlocking clasps both on the pusher and on the embolic coil.

5 U.S. Patent No. 5,261,916, to Engelson shows a combination pusher/vaso-occlusive coil assembly joined by an interlocking ball and keyway type coupling.

U.S. Patent No. 5,304,195, to Twyford et al., shows a pusher/vaso-occlusive coil assembly having a fixed proximally extending wire carrying a ball on its proximal end and a pusher having a similar end which two tips are interlocked and disengaged when expelled from the distal tip of the catheter.

10 U.S. Patent No. 5,312,415, to Palermo shows a method for discharging numerous coils from a single pusher by using a guidewire which has a section capable of interconnecting with the interior of a helically wound coil.

U.S. Patent No. 5,350,397, to Palermo et al. shows a pusher having a throat at its distal end and a pusher through its axis. The pusher throat holds onto the end of an embolic coil and releases that coil upon pushing the axially placed pusher wire against member found on the proximal end of the vaso-occlusive coil.

Other mechanically detachable embolism forming devices are known in the art.

Each of the patents listed herein is specifically incorporated by reference.

20 Guglielmi et al. shows an embolism forming device and procedure for using that device which, instead of a mechanical joint, uses an electrolytically severable joint. Specifically, Guglielmi et al. desirably places a finely wound platinum coil into a vascular cavity such as an aneurysm. The coil is delivered endovascularly using a catheter such as those described above. After placement in the aneurysm, the coil is severed from its insertion core wire by the application of a small electric current to that core wire. The deliverable coils are said to be made of a platinum material. They may be 1-50 cm or longer as is necessary. Proximal of the embolic coil, as noted above, is a core wire which is typically stainless steel. The core wire is used to push the platinum embolic coil into vascular site to be occluded.

30 Other variations of the Guglielmi et al. technology are found in U.S. Patent No. 5,354,295.

None of the references described above teaches or suggest an implant assembly having a highly resistive or insulative joint between that implant and a cooperating electrolytically severable delivery joint.

### SUMMARY OF THE INVENTION

This invention is an implant assembly in which an implant is placed in the human body using an electrolytically severable joint. The implant is isolated from the electrical circuit within the body by an insulative or high resistance member. The implant may be a vaso-occlusive device, stent, *vena cava* filter, or any other implant which may be delivered via a catheter. Desirably, the device includes a core wire having a distal tip, which distal tip or implant may be introduced into the selected site. The core wire is attached to the distal tip or implant in such a way that the implant may be electrolytically detached by application of a current to the core wire.

The improvement involves the use of an insulative or highly resistive member proximal of the implant. The resistive or insulating member may be any suitable material such as inorganic oxides, glues, polymeric inserts, polymeric coverings, etc. This insulative or highly resistive layer or joint appears to focus the current flow through the sacrificial electrolytic joint and thereby improves the rate at which detachment of the implant occurs.

### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows the overall layout of delivery system showing the typical major parts for delivering an implant using the improvement of this invention.

Figures 2-11 show respectively cross sections depicting various insulating or resistive joints which electrically isolate implants.

Figure 12 shows a partial cross section of an electrolytic joint and a vaso-occlusive braid all made according to this invention.

Figures 13 and 14 show helically wound vaso-occlusive coils having secondary shapes which may be deployed using the procedures described herein.

Figure 15 shows a stent implant using the improvements of this invention.

Figure 16 shows a *vena cava* filter which may be deployed using the improvements of this invention.

Figures 17A and 17B show, in schematic form, a procedure for deploying the inventive vaso-occlusive device of this invention.

Figure 18 is a graph of detachment times for a comparative commercial GDC device.

Figures 19 and 20 are graphs of detachment times for variations of the GDC device made according to the invention.

### DESCRIPTION OF THE INVENTION

As noted above, the Guglielmi et al system for deploying an implant into the human body uses a core wire, an electrolytic sacrificial joint, and the implant to be deployed. A power supply is needed to provide power for electrolysis of the joint. The core wire is typically insulated on its outer surface from near the proximal end of the wire and along the wire to the electrolytic sacrificial joint. The implant typically forms a portion of the circuit through the body. This invention substantially removes the implant itself from that circuit thereby apparently focusing the current flow at the electrolytic joint where it is needed for electrolysis.

Figure 1 shows a system for introducing and deploying the implant made according to the invention. The system (100) includes a catheter (102) which is made up of an elongate tubular member, typically made from a polymeric material and often reinforced with a coil or braid to provide strength or obviate kinking propensities. Catheter (102) is shown with a pair of radiopaque markers (106). The radiopaque markers (106) allow visualization of the distal end (104) of the catheter so to compare it with the coincidence of the implant. Catheter (102) is also shown with a proximal fitting (108) for introduction of dyes or treatment materials. Within the lumen of catheter (102) is a core wire (110) extending both proximally of catheter (102) and distally. On the distal end of core wire (110) may be seen the electrolytic joint (112) and the implant (114). In this instance, implant (114) is shown to be a helically wound vaso-occlusive coil. Generally, all of core wire (110) is electrically insulated from a point near the proximal end of core wire (110)



continuously to electrolytically severable joint (112). Electrolytically severable joint (112) is bare and is relatively more susceptible to electrolysis in an ionic solution such as blood or most other bodily fluids than is the implant (114).

The most proximal end of core wire (110) is also left bare so that power supply (116) may be attached. The other pole of the power supply (116) is typically attached to a patch (118). The patch is placed on the skin to complete the circuit from the power supply (116), through the core wire (110), through electrolytic joint (112), through the ionic solution in the body, and back to a patch (118) to the power supply (116). Other return routes may be used as the designer sees fit.

Central to this invention is electrical isolation of implant (114) from core wire (110) and electrolytically severable joint (112). Without wishing to be bound by theory, it is believed that isolation of the implant (114) prevents or lessens current flow through the implant (114) itself and concentrates the current flow through the electrolytic joint (112).

Figure 2 shows a close-up of the more distal portion of one variation of the invention. This variation includes the core wire (110) and the attached implant (120). Typically, core wire (110) will be conductive but covered with a insulative layer (111) both proximal and distal of electrolytically severable joint (112). The interior of core wire (110) is physically attached to implant (120). In this variation of the invention, implant (120) is a helically wound coil.

In this invention, a highly resistive or insulative layer or member electrically isolates implant (120) from core wire (110). In this variation of the invention, the insulating layer (111) on the core wire (110) is simply continued to the end of the core wire (110). An optional bushing (114) is placed on the core wire (110) to further separate it from implant (120). Optional bushing (114) may be of any suitable material since it operates merely as a spacer. Insulating layer (111) may be polytetrafluoroethylene (e.g., Teflon), polyparaxylxylene (e.g., Parylene), polyethyleneterephthalate (PET), polybutyleneterephthalate (PBT), cyanoacrylate adhesives, or other suitable insulating layer, but preferably is polymeric and most preferably is PET.

The coil making up this variation (and other coil-based variations) of the invention is generally of a diameter in the range of 0.00025 inches and 0.006 inches. Wire of such diameter is wound into a primary form having a diameter of between 0.003 and 0.025

inches. For most neurovascular indications, the preferable primary coil diameter is preferably between 0.008 and 0.018 inches.

The axial length of the primary coil will usually fall in the range of 0.5 to 100 cm, more usually 2.0 to 40 cm. Depending upon usage, the coil may well have 10-75 turns per centimeter, preferably 10-40 turns per centimeter. All of the dimensions here are provided only as guidelines and are not critical to the invention. However, only dimensions suitable for use in occluding sites within the human body are included in the scope of this invention.

Figure 2 shows a close-up of another variation of the invention including the more distal portion of the core wire (110) and the attached implant (120). In this variation of the invention, implant (120) is a helically wound coil having a stretch resisting member (134) through its center lumen. The anti-stretch member (134) may be of any suitable material, e.g., metallic wire or polymeric threads. Preferred are polymeric threads comprised of a member selected from the group consisting of polyethylene, polypropylene, polyamides, and polyethyleneterephthalate although almost any polymeric material which is formable into a fiber is quite suitable. The stretch resisting member is simply designed to prevent the coil (130) from stretching in the event that core wire (110) must be withdrawn or repositioned to change the position of the implant (120).

The stretch resisting member (134) is attached to an interior anchor coil (136) having a distal hook (138) to which the stretch resisting member (134) is attached. An optional bushing (140) is present and attached to the metallic center of the core wire (110). In this variation of the invention, either or both of the optional bushing (140) or interior anchor coil (136) may be of an oxide-forming material such as tantalum and the like. We have found that when tantalum or other such refractory forming materials are subjected to welding operations as may be found when assembling this device, an apparently oxidic, but highly electrically resistive layer is formed at the junction of the tantalum and its neighbor.

Figure 4 shows another variation (150) of the inventive implant assembly. In this variation, bushing (152) is formed of an oxidic or insulative-forming material and is included to form such a resistive layer during operations to weld the metallic center (154) to bushing (152).

Figure 5 shows another variation (158) of the inventive implant assembly. In this variation, the implant (120) is attached to the core wire (110) and at the same time is electrically insulated from the metallic center (154) of core wire (110) by the use of a glue or thermopolymer (156) made from a suitable polymer, e.g., a thermoplastic, preferably comprising a member selected from the group consisting of polyethylene, polypropylene, polyamides, and polyethyleneterephthalate.

An "oxide forming material" or "insulator-forming material" as those terms are used herein are materials which, under the imposition of an appropriate electrical current or other such excitation, will form an insulating, preferably oxide, layer. One such material is the metal tantalum and certain of its alloys. Other insulation forming materials or oxide forming materials include zirconium.

Although the use of solid insulation forming material is shown in Figures 3 and 4, the use of an insulation forming material in a layer is also contemplated. Such a layer may be plated, sputtered, painted, heat shrunk, glued, or melted onto the appropriate part.

Figure 6 shows another variation of the invention, in this case using a polymeric insert between core wire (110) and helical deployment coil (120). Electrolytically severable joint (112) is also shown. The polymeric insert (121) typically includes a radiopaque marker coil (123) and is simply slid over the distal tip of core wire (110) and into the lumen of helical coil (120). Once so assembled, this assemblage is heat-treated to cause the various portions to adhere to each other. As is the case with any of the other variations shown herein, it may be desirable to place circumferential ribs on the distal tip of core wire (110) to provide a more suitable bond for the polymeric insert (121). Care must be taken, of course, to ensure that polymeric plug (121) contains no materials (e.g., dyes or opacifiers) which would enhance the conductivity of the plastic. It is the task of polymeric insert (121) to insulate core wire (110) from deployable helical coil (120) so the electrolytic joint (112) is easily and readily detached. It should be noted, that although the radiopaque coil (123) is highly desirable, in this invention, it is completely optional.

Figure 7 shows still another variation of the invention. This variation is a similar concept both to the polymeric plug variation shown in Figure 8 and to the variation shown in Figure 2 involving a stretch-resistant member.

In this variation, polymeric plug (125) is again slipped over the distal portion of core wire (110) and into the proximal portion of helical coil (120). The assembled joint is heated so to allow whatever thermal plastic, maybe in a polymeric insert (125) to flow and secure the detachable implant (121) to the core wire. Electrolytically severable joint (112) is also shown.

The major difference between this variation and others seen before is in the presence of coil (127) fixedly attached to stretch resisting member (129). Of particular interest, is the fact that coil (129) is soldered or preferably welded to detachable helical coil (120) in the region (131). Coil (127) should be a material similar to that of helical detachable coil (120) to prevent any untoward happenings during the severance of electrolytic joint (112) by provision of voltage couples or the like.

Figure 8 shows still another variation of the invention of the invention in which a polymeric plug is used to separate the core wire (103) from the deployable implant (107). Incidentally, core wire (103) is shown to have an external marker (105) at its proximal end. Core wire (103) additionally has, adjacent detachment region (109), a surface (111) which is cut on a bias or at an angle to the axis of core wire (103). As is discussed in a number of prior patents assigned to Target Therapeutics Incorporated, this biased surface (111) enhances the physician's ability to detach the implantable device (107) from core wire (103) once electrolysis or electro-erosion is completed. This surface (111) is formed by use of a plug (113) which is typically polymeric in nature. A series of coils (115) and (117) are also shown in this variation. Coils (115) and (117) are typically produced of radiopaque material. They are positioned to allow easy visualization of the detachment region (109). The depiction found in Figure 8 further has a shrink wrapped coating (119) on the exterior of the device proximal of the detachment area (109).

In this instance, the proximal end of the implant (107), distal of the detachment zone (109) is constructed of a number of polymeric portions which allow for easy and practical assembly of the overall device. In particular, radiopaque coil (121) is surrounded by polymeric region (123). It is often the case that assembling the device shown in Figure 8, the bare distal end of core wire (103) will first be wrapped with coil (121) and then the so-wrapped coil (121) will then be dipped in molten polymeric material to form the polymeric region (123). A polymeric plug, typically thermal plastic (125) is also

inserted into the proximal end of implant (107). A polymeric coating, typically thermal plastic and typically a shrink wrap is then placed over the two polymeric masses (123) and (125). Upon application of appropriate, heat, outer covering (127) serves to attach the distal end of core wire (103) with the proximal end of implant (107). In many instances, the polymers used variously in regions (123), region (125), and covering (127) are the same. Desirably, they are miscible with each other upon application of appropriate heat. It is also appropriate that they merely bind to each other in a well defined way.

This variation of the device is quite easy to assemble and the radiopaque coil (123) gives the physician-user a well defined end point for introduction of the implant (107) into the aneurysm or other cavity.

Figure 9 shows a variation of the invention similar to that found in Figure 8 except that it shows the use of a strain resistant vaso-occlusive device. For purposes of this description all of the core wire (103) proximal of detachment zone (109) is the same as is shown in Figure 8. Similarly, the distal end of coil wire (103) includes a radiopaque coil (121) initially covered by a polymeric covering or region (123). In this instance, the polymeric region (131) placed within the distal end of vaso-occlusive implant (107) includes a coil (133) having a distal loop (135) thereon. That distal loop is, in turn, attached to a stretch resisting member (137) of the type discussed at length above with regard to Figure 3. Again, this device may be assembled using a thermoplastic or shrink wrap covering (139) placed exteriorly about polymeric region (123) and the distal end of implant (107).

Figures 10 and 11 show still another variation of the insulative joint. In particular, Figure 10 shows a implant (141) located distally of the region (109). In this instance, the distal end of the core wire has a radiopaque coil (143) wrapped around. Central to this variation of the invention is the presence of an anchoring member (145). Anchoring member (145) typically has a small loop (147) allowing for connection of the stretch resisting member (149). It is desirable to include a polymeric region (151) distally of anchoring member (145). Polymeric region (151) may be placed in the implant (141) in such a way that it makes the stretch resisting member (149) adhere well to the anchor member (145). Anchor member (145) should have a diameter which is larger than that of the interior of the implant (141) so that should the distal end of implant (141) be pulled

strongly, the end of anchor member (145) not be able to pass through the lumen of implant member (141). Again, as with the variations shown in Figures 8 and 9, the exterior of the joint region shown in Figure 10 may be all assembled using a polymeric tubing, preferably thermal plastic, which adheres to and joins all of the noted pertinent parts together.

5           Figure 10 shows a similar variation of the anchor member (153) but is somewhat different in that the loop (155) for attaching to the strain resisting member (149) is larger and there is no polymeric region (151) as was shown in Figure 10.

10           The variation shown in Figures 8 and 9 and especially those shown in Figures 10 and 11 are particularly useful when utilizing the insulating joint of this invention in combination with very flexible vaso-occlusive coil as the implant. Such a highly flexible vaso-occlusive coil is described in U.S. Patent Nos. 5,669,931 (to Kupiecki et al.) and 5,690,666 (to Berenstein et al.). The entirety of these patents is hereby incorporated by reference.

15           Although the preferred variation of the invention is that found in the Figures discussed above wherein a helical coil implant is fixably attached distally of electrolytically severable joint (112), other implants are suitable. For instance, Figure 12 shows another variation of the inventive device (160) in which the implant is a vaso-occlusive braid (162), either woven or unwoven. The electrolytically severable joint (164) is shown proximally of vaso-occlusive braid (162). In this variation, the core wire is insulated with a tubular member (168) and a bushing (170). A stabilizing coil (172) is also depicted on the distal end of core wire (166). Bushing (170) and covering (168) serve to electrically insulate core wire (166) from the surrounding ionic fluid. These coverings along with the isolating joint (not shown in cross section in this Figure) found on vaso-occlusive woven braid (162) apparently focus the electrolysis process on the electrolytically severable joint (164).

25           When the implant is a vaso-occlusive device, the shape of the device may be any of a number of suitable overall shapes to promote occlusion of the selected interior body space. In particular, when the implant is a helical coil, many shapes are known for treatment of particular abnormalities. Figures 13 and 14 show useful devices for treatment of arterio-venous malformations (AVM) and aneurysms. Specifically, Figure 13 shows a

vaso-occlusive coil which has a secondary conical shape. A "secondary" shape is meant to include any form in which a wire is first formed into a first helical form and that first helical form is wound into a second form, possibly, but not necessarily, helical. Secondary forms include generally spherical, ovoid, elongated, and any other form into which the device will "self-form" upon relaxation either within a body open region or simply outside the delivery catheter. As was noted above, vaso-occlusive devices are introduced through a catheter. Pushing the vaso-occlusive device through the catheter uses that first linear configuration which approximates the shape of the interior of the catheter. Secondary shape such as shown in Figures 13 and 14 are formed when the vaso-occlusive device is allowed to exit the distal end of the catheter. The secondary shape of the vaso-occlusive device (180) shown in Figure 9 is, as noted just above, conical in form.

Figure 14 shows a variation (182) of the inventive device in which two sections of the vaso-occlusive device have different secondary diameters.

Each of the vaso-occlusive devices described herein may also have attached fibrous materials to increase their thrombogenicity.

Figure 15 shows a variation (190) of the inventive device in which the implant is a stent (192). Core (194) is also shown with an electrolytically erodable joint (196).

The stent shown in Figure 15 is a variation of a self expanding stent typically made of a super-elastic alloy material, typically a nickel-titanium alloy (e.g., nitinol), that is well known in the art. The device has a zig-zag pattern of a metallic wire which is maintained in the noted and secondary form by a filament (198) which is woven through the bends of the stent to maintain the secondary shape. The primary shape is simply the shape shown but with a significantly lower diameter. The form of the stent is not important to the invention but is only illustrative of the form an implant may take

Figure 13 shows the expanded form of an implant (200) which may be used as a *vena cava* filter. *Vena cava* filters are well known in the art and are used to prevent the flow of blood clots distally in the vasculature. These blood clots would eventually be the site of occlusive strokes in the brain if allowed to travel distally. In any event, implant (200) shows the *vena cava* filter member (202), the electrolytically severable joint (204) and the push wire or core wire (206).

Figures 17A and 17B show placement of the inventive devices, specifically the vaso-occlusive variations of the invention, within the human body. Figure 17A shows the placement within a vessel (200) with a tip of catheter (202) placed near aneurysm neck (204). The aneurysm itself is nominated (206). Vaso-occlusive device (208) is fed into aneurysm (206) at least until the sacrificial link or joint (210) (hidden within catheter (202) at this step) is exposed beyond the distal tip of catheter (202). A positive electric current of approximately 0.01-2 milliamps at 0.1-6 volts as applied to core wire (212). An embolic mass is then formed within aneurysm (206). The negative pole (214) of power supply (216) is typically placed in electrical contact with the skin so to complete the circuit. The vaso-occlusive device (208) is detached from core wire (212) by electrolytic disintegration of sacrificial link (210).

After sacrificial link (210) is at least mostly dissolved by electrolytic action, typically in less than two minutes and most often in less than one minute, the core wire (212), catheter (202), are removed from vessel (200) leaving aneurysm (206) occluded as shown in Figure 17B.

This procedure is typically practiced under fluoroscopic control with local or general anesthesia. A transfemoral catheter may be used to treat cerebral aneurysm and is usually introduced at the groin. When the vaso-occlusive device (208) is isolated by a highly resistive material as is contemplated this invention, it is not affected by electrolysis. When the core wire (212) and the pertinent portions of the supporting coils at the distal tip of the core wire (when utilized) are adequately coated with insulating coverings, only the exposed portion of the sacrificial link (210) is affected by the electrolysis.

#### EXAMPLE

We compared detachment times for commercially available Guglielmi Detachable Coils (GDC) with those for a variation of the invention similar to that shown in Figure 3. We constructed three sets of ten implant assemblies. The first set (Figure 18) were commercial GDC assemblies as modified below. The second set (Figure 19) had tantalum interior anchor coils ((136) in Figure 3) and a distal hook (138) to which the stretch resisting member (134) was attached. The third set (Figure 16) were similar to those



described in regard to Figure 6 incorporating a PET insulator between the detachable coil and the electrolytic joint. The implants on each were platinum coils.

On set no 2., the platinum bushing (140) was included and attached to the metallic center of the core wire (110). The assembly of tantalum interior anchor coil, platinum bushing, and core wire (110) was welded together.

To exaggerate and lengthen the detachment times for each set, as would be the case when an implant is inserted into an aneurysm already having a number of platinum coils with vestigial remaining stainless steel stubs remaining from prior detachments and having electrical contact with those coils, an additional stainless steel wire of about one inch length was added to the detachable coils. The resulting detachment times for the coils were increased by as much as ten-fold as is sometimes seen clinically.

Each of the comparative commercial GDC's and the inventive variations were placed in a saline bath and subjected to a constant amperage of 1 ma and a resulting voltage of between 1.5 and 2.0 volts. The time for electrolytic erosion of the joint was measured. As shown in Figure 14, the average time for detachment of the commercial GDC coil was 454.9 seconds. As shown in Figure 19, the average time for detachment of the inventive variation GDC coil using tantalum insulator coils was 125.1 seconds. As shown in Figure 20, the average time for detachment of the inventive variation GDC coil using a PET insulator sock was 38 seconds.

Many alterations and modifications may be made by those having ordinary skill in this art without departing from the spirit and scope of the invention. The illustrative embodiments have been used only for the purposes of clarity and should not be taken as limiting the invention as defined by the following claims.

**WE CLAIM AS OUR INVENTION:**

1. An implant assembly for placement of an implant in the human body comprising:

(a.) said implant member having a proximal end and a distal end, and

(b.) an electrolytically severable joint situated to release said implant member upon application of electrical energy to said electrolytically severable joint, said electrolytically severable joint being relatively more susceptible to electrolysis in an ionic solution than is said implant member,

wherein said implant member is electrically isolated from said electrolytically severable joint.

2. The implant assembly of claim 1 wherein said electrical isolation is due to an insulative or highly resistive layer interposed between implant member and said electrolytically severable joint.

3. The implant assembly of claim 2 wherein said insulative or highly resistive layer comprises tantalum oxide.

4. The implant assembly of claim 2 wherein said insulative or highly resistive layer comprises a polymer.

5. The implant assembly of claim 4 wherein said insulative or highly resistive layer comprises a thermoplastic.

6. The implant assembly of claim 4 wherein said insulative or highly resistive layer comprises a member selected from the group consisting of polyethylene, polypropylene, polyamides, and polyethyleneterephthalate.

7. The implant assembly of claim 2 wherein said insulative or highly resistive layer comprises an oxide forming material.

8. The implant assembly of claim 1 wherein the implant member is a stent.

5 9. The implant assembly of claim 1 wherein the implant member comprises a *vena cava* filter.

10. The implant assembly of claim 1 wherein the implant member comprises a braid.

10 11. The implant assembly of claim 1 wherein the implant member comprises a helically wound coil.

12. The implant assembly of claim 11 wherein the helically wound coil implant member has a proximal end and a distal end and further comprises a stretch resistant member extending at least partially from said proximal end to said distal end.

15 13. The implant assembly of claim 12 wherein the stretch resistant member comprises a member selected from the group consisting of polyethylene, polypropylene, polyamides, and polyethyleneterephthalate.

20 14. The implant assembly of claim 11 further including a helically wound coil situated proximally in the lumen of said helically wound implant member and fixedly attached to said stretch resistant member.

25 15. The implant assembly of claim 14 wherein said helically wound coil situated proximally in the lumen of said helically wound implant member is welded to said helically wound implant member.

30 16. The implant assembly of claim 1 wherein said implant member proximal end has a radio-opaque member placed thereon.

16. A method for introduction of an implant into a space within the human body comprising:

1.) placing a delivery catheter distal tip near a selected space within the human body,

2.) introducing an implant assembly comprising:

(i.) said implant member having a proximal end and a distal end, and

(ii.) an electrolytically severable joint attached to said implant member proximal end, said electrolytically severable joint being relatively more susceptible to electrolysis in an ionic solution than is said implant member,

wherein said implant member is electrically isolated from said electrolytically severable joint, into said catheter,

3.) placing said implant member into said selected space, and

4.) electrolytically detaching said implant member from said implant assembly.

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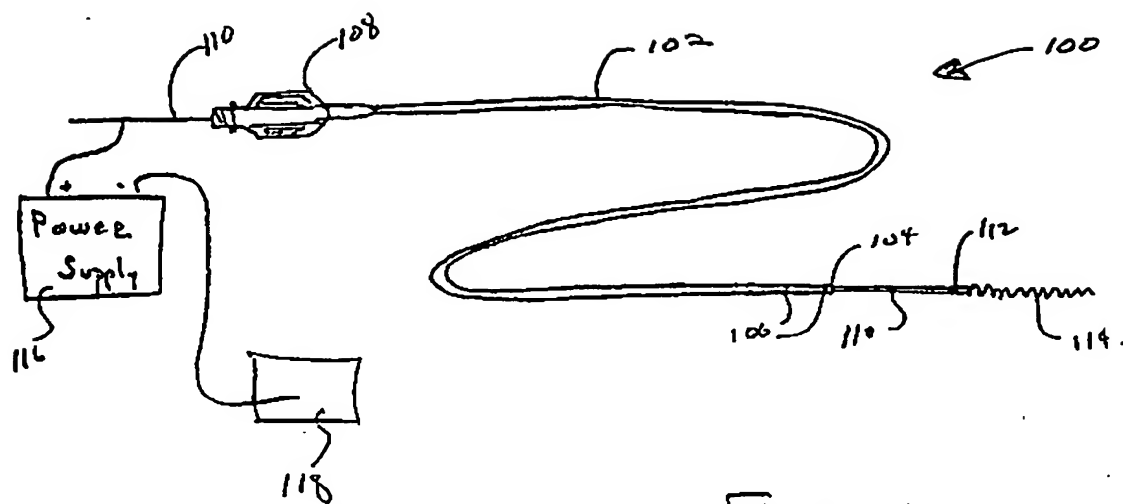
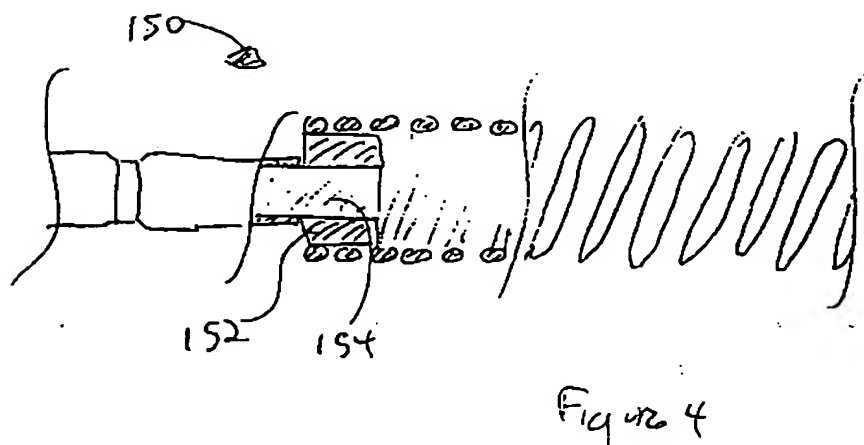
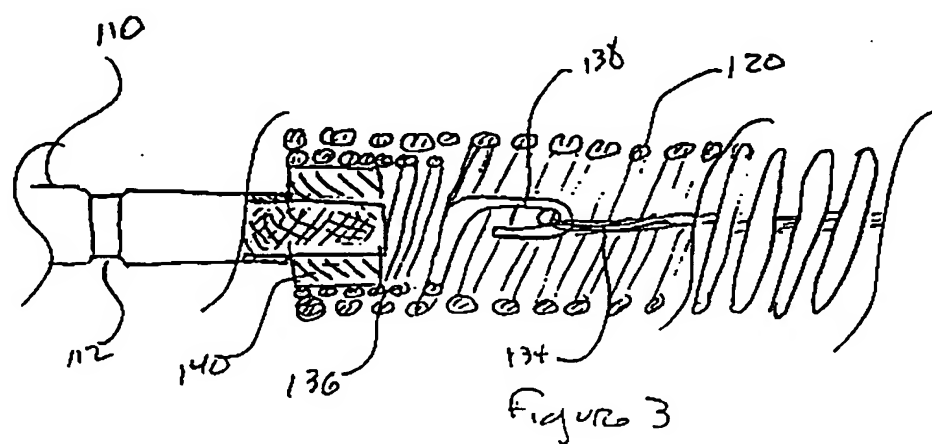
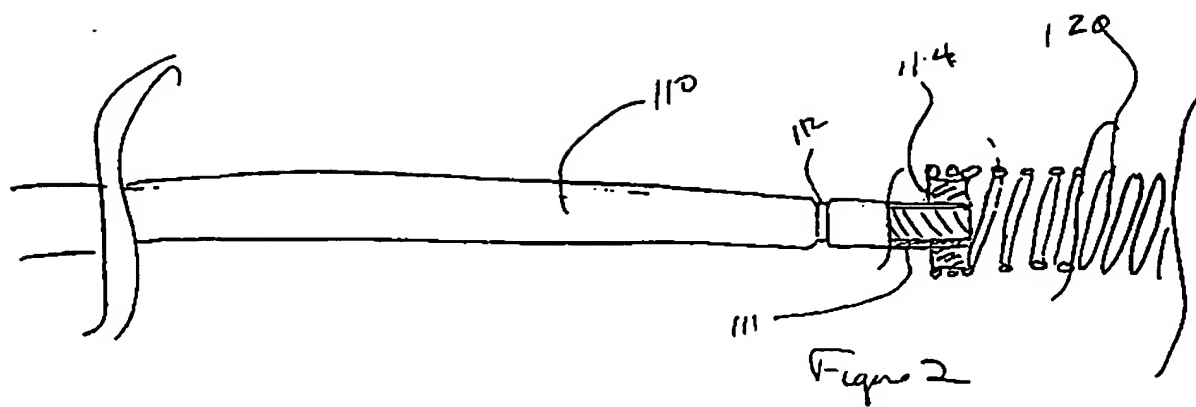


Figure 1



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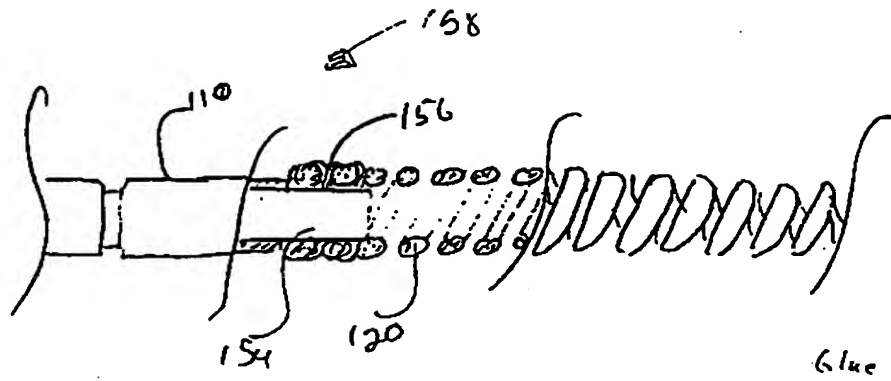


Figure 5

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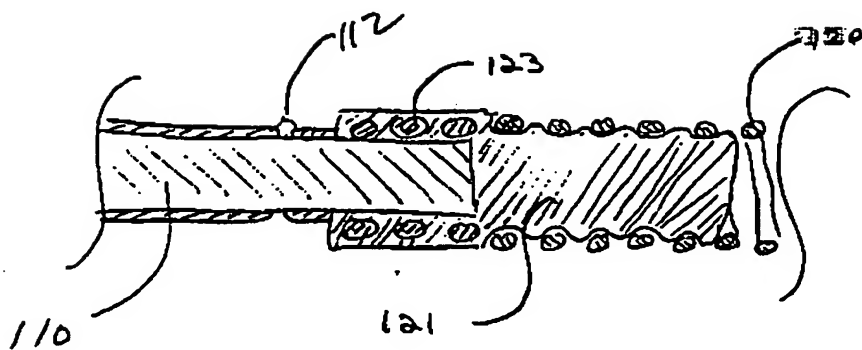


Figure 6

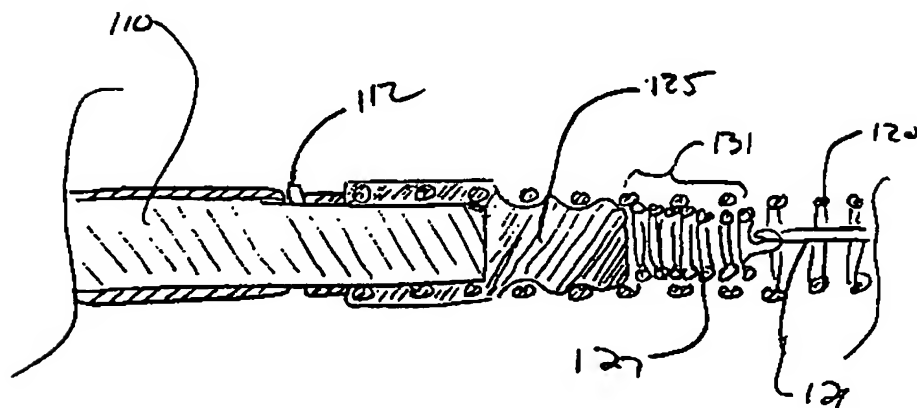


Figure 7



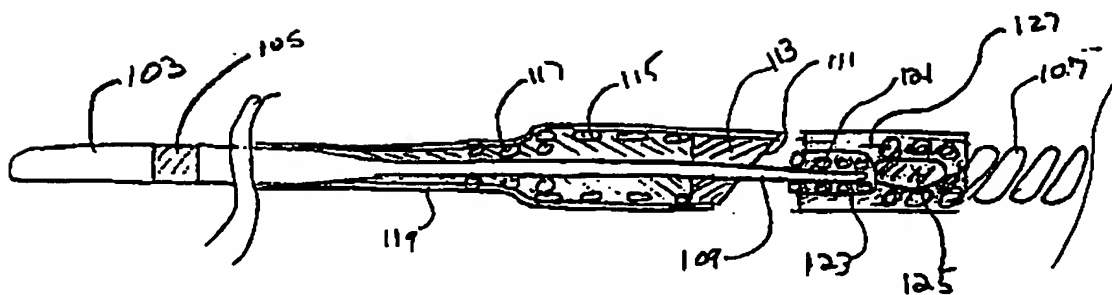


Figure 8

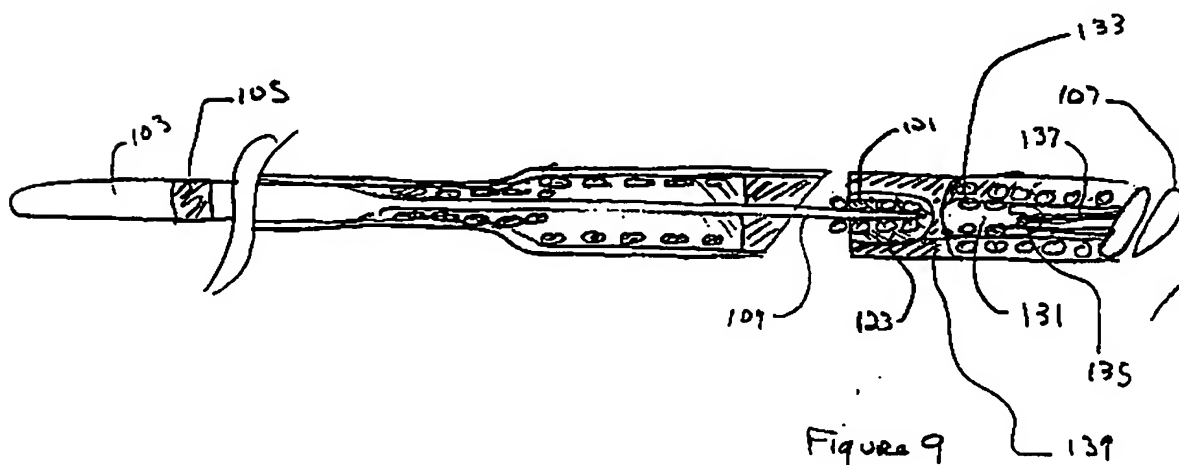


Figure 9

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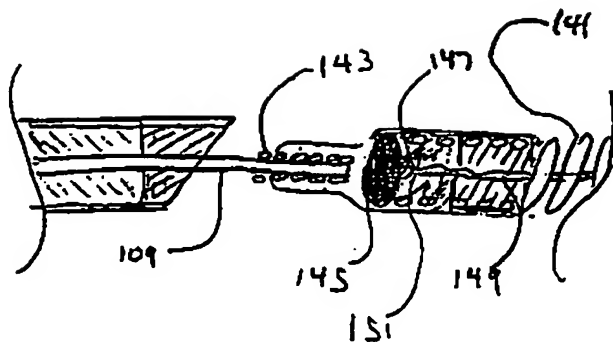


Figure 10

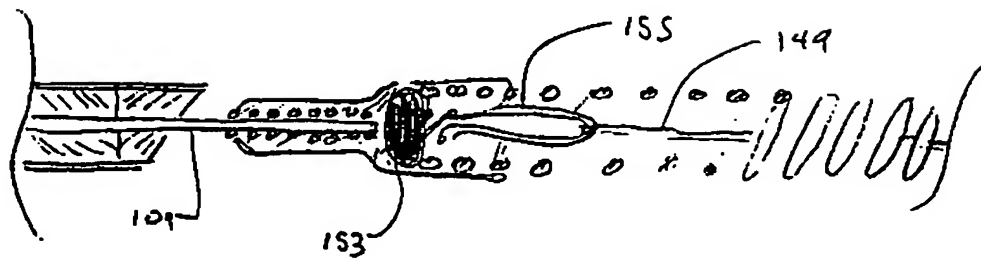


Figure 11

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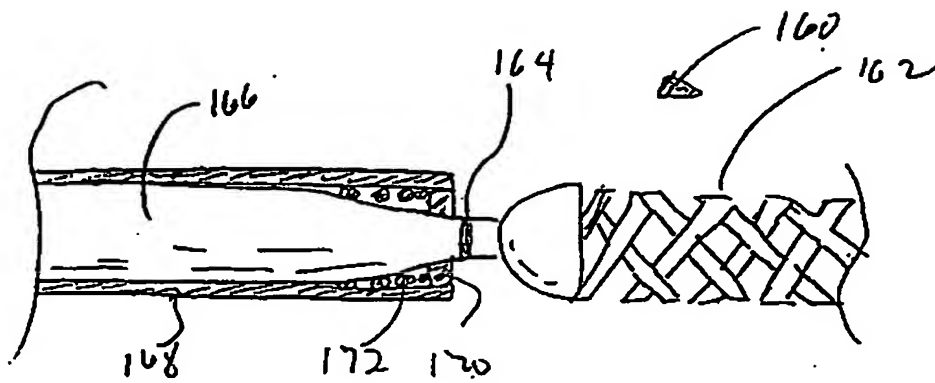


Figure ~~12~~ 12



Figure ~~13~~ 13

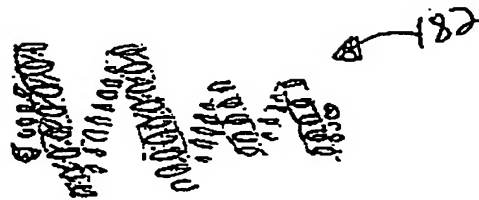


Figure ~~14~~ 14

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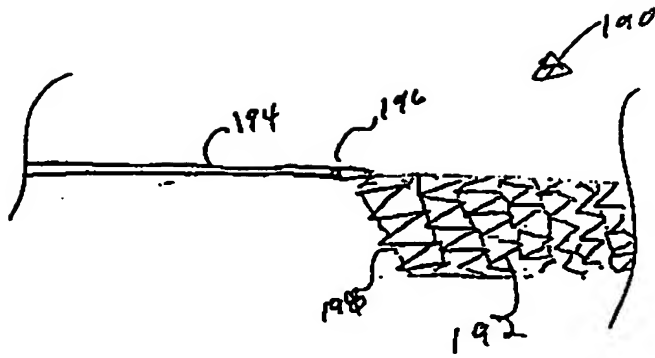


Figure 15

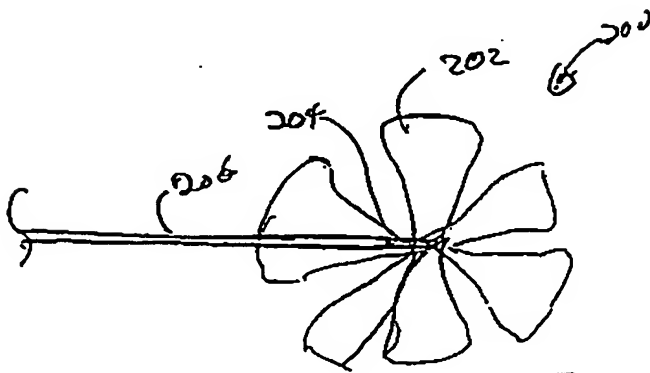
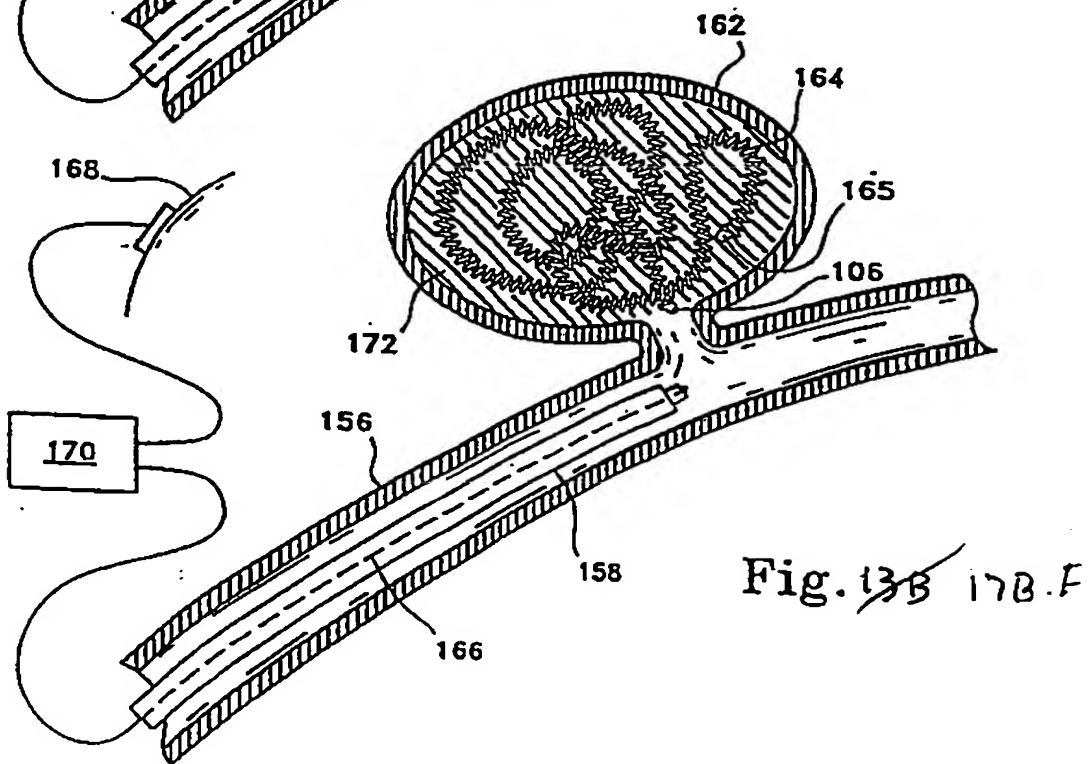
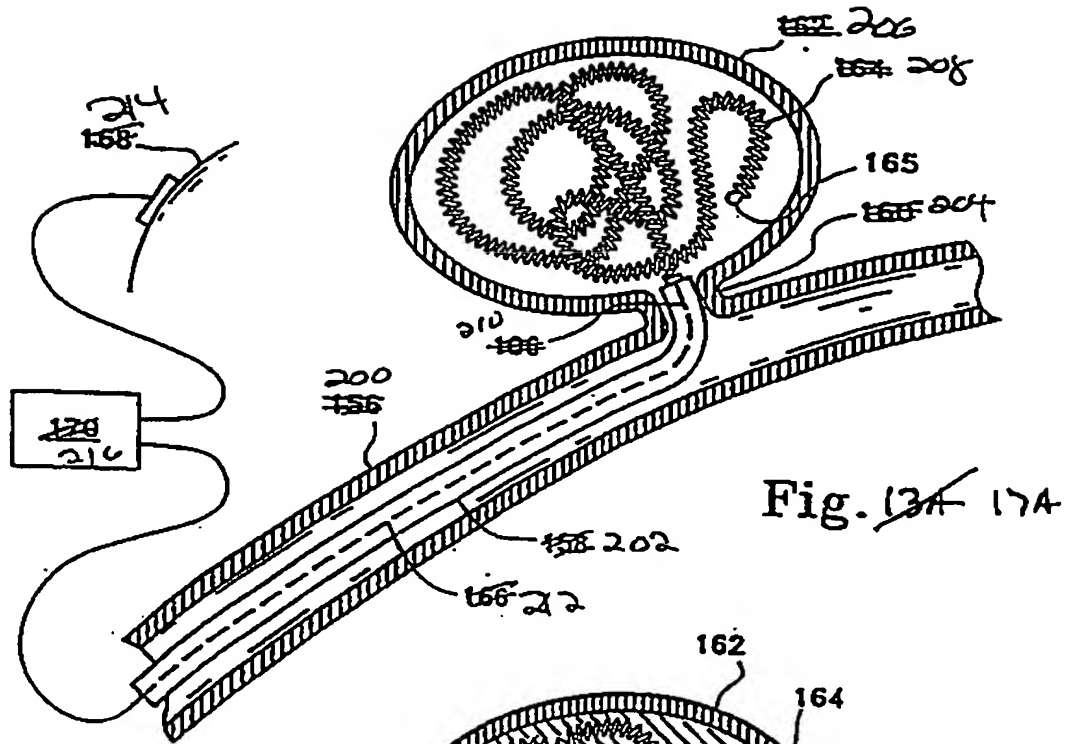


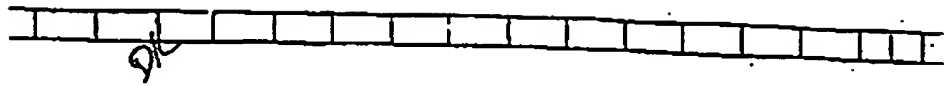
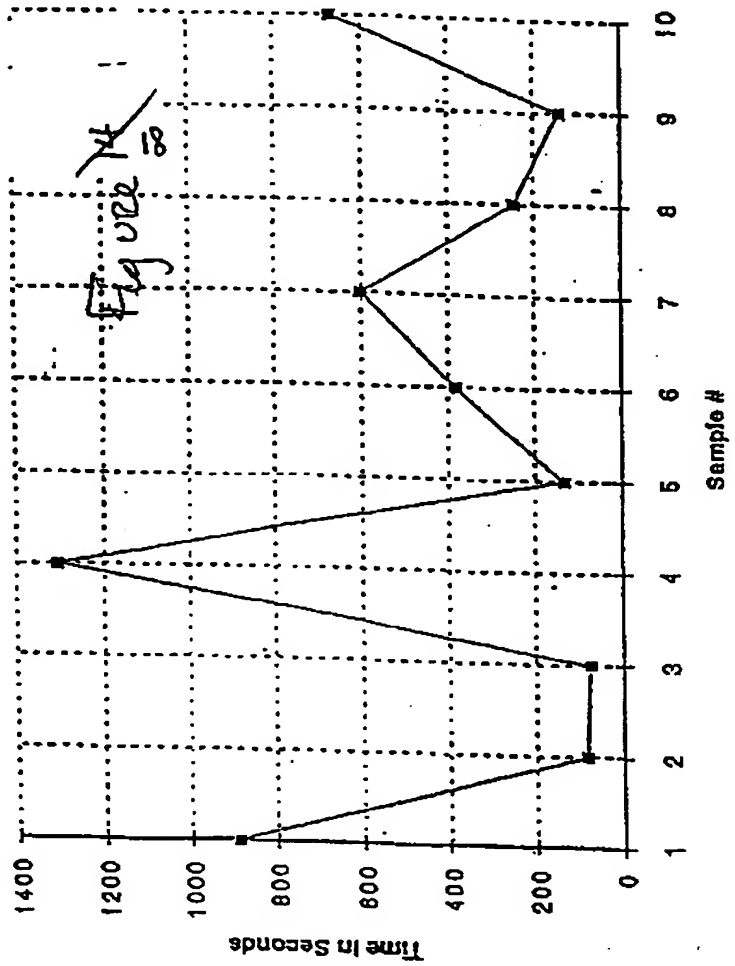
Figure 16

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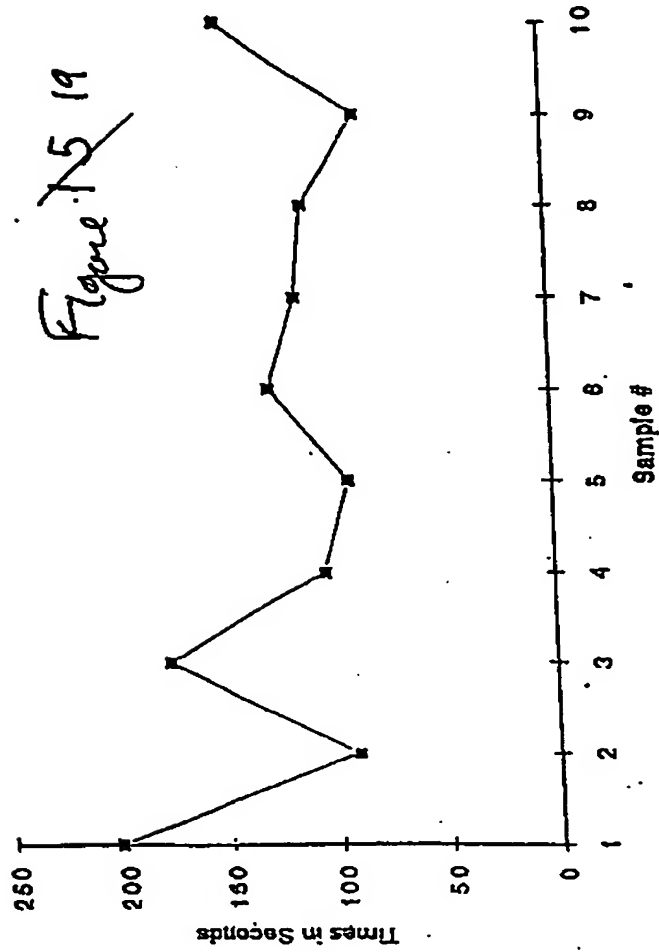
10/12

Sample #	Time In Seconds
1	890
2	86
3	79
4	1308
5	136
6	385
7	603
8	246
9	143
10	673
Average	454.90
Dev.	409.81



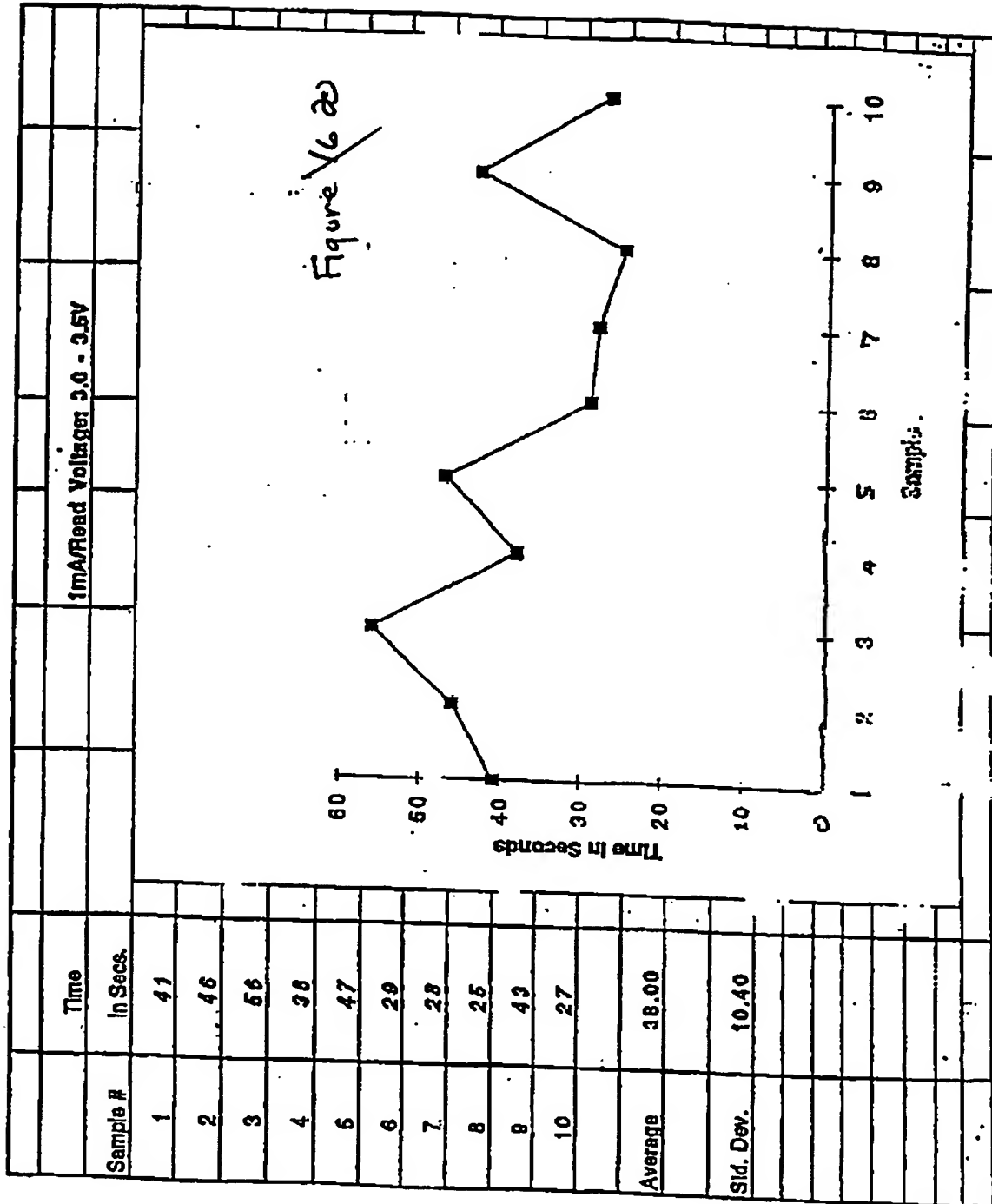
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Figure 15 19



Sample #	Time In Secs.
1	202
2	92
3	177
4	106
5	93
6	127
7	114
8	110
9	85
10	146
Average	125.10
Std. Dev.	38.78

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# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 98/17885

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/12 A61F2/01 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 719 522 A (TARGET THERAPEUTICS INC) 3 July 1996 see column 7, line 17 - column 8, line 4; figures 6,7	1,2,4, 8-11
A	US 5 582 619 A (KEN CHRISTOPHER G M) 10 December 1996 see column 3, line 28 - column 4, line 17; figure 1	1,12,13
A	US 5 540 680 A (GUGLIELMI GUIDO ET AL) 30 July 1996 see column 11, line 9 - line 20; figure 6	1,4-6
A	US 4 945 342 A (STEINEMANN SAMUEL G) 31 July 1990 see abstract see column 8, line 19 - line 31; figure 2	1,3,7
-/-		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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Date of the actual completion of the international search

11 December 1998

Date of mailing of the international search report

17/12/1998

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Hansen, S

# INTERNATIONAL SEARCH REPORT

Internat. Application No.

PCT/US 98/17885

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 010 759 A (BOER GERARD B M) 8 March 1977 see abstract; figure 1	1,3,7
A	US 5 354 295 A (GUGLIELMI GUIDO ET AL) 11 October 1994 cited in the application see abstract; figure 1	1
A	US 5 122 136 A (GUGLIELMI GUIDO ET AL) 16 June 1992 cited in the application see abstract; figure 1	1

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/ 17885

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: Claim 16  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claim 16: Rule 39.1 (iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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Information on patent family members

Internat. Application No

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